

## REMARKS

Reconsideration of the above-identified application in view of the arguments set forth is respectfully requested.

Claims 80-82 and 85-86 are pending. Claims 83-84 have been deleted in response to a restriction requirement. Applicants reserve the right to pursue these claims in one or more divisional applications. Claims 80-82 have been amended as discussed in more detail herein. Claims 85 and 86 have been added as explained below. No new matter has been added as a result of the amendment of claims 80-82 and the addition of claims 85 and 86.

### Election/Restrictions

In the Office Action, the Examiner states that newly submitted claims 83-84 are directed to an invention that is independent and distinct. Specifically, the Examiner stated that these claims are drawn to detecting a polypeptide which is independent and distinct from a method of detecting nucleic acids. While Applicants disagree with the Examiner's position, in an effort to expedite prosecution, claims 83-84 have been deleted. Applicants reserve the right to pursue these claims in one or more divisional applications.

### Claim Objections

Claims 80-82 are objected to because of certain informalities. Specifically, the Examiner stated that claim 80 lacked either a modifier "a" before the recitation of "breast cell" or that the term "breast cell" should be plural. As Applicants will explain in more detail below, claim 80 has been amended to remove the reference to a "breast cell". The Examiner stated that claim 81 is "grammatically incorrect" in the recitation in lines 7-8 of "detection of a BS106 gene product is detected in the sample". Applicants thank the Examiner for kindly pointing out this grammatical error. Claim 81 has been amended to correct this grammatical error. Claim 82 was objected to as containing a misspelling. Applicants thank the Examiner for pointing out this misspelling. Claim 82 has been amended to correct said misspelling.

In view of the aforementioned amendments to claims 80-82, Applicants submit that all of the claim objections have been addressed and that this objection should be removed.

#### Claim Rejections – 35 U.S.C. Section 112

Claims 80-82 are rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner has raised a new matter rejection. The Examiner states that the specification does not specifically support a method of detecting a breast cell in a sample taken from any tissue other than breast or for a method of detecting a malignancy of breast tissue by providing a sample from any non breast tissue and determining if a BS106 gene product is present, the presence of such being indicative of breast cancer. While not agreeing with the Examiner's position, Applicants have amended claims 80-82 in order to expedite prosecution. In view of the amendments to claims 80-82, Applicants submit that this rejection should be withdrawn.

Claims 80-82 are also rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states several reasons for the rejection which are reiterated below. Applicants respectfully traverse the rejection.

First, the Examiner states that the specification does not teach that the BS106 gene product, as defined in the specification, is specific for breast cells, or the detection of such is an indication of breast disease. Applicants submit that the claims have been amended, as stated above, so that they no longer recite "A method of detecting breast cell". With respect to determining whether the BS106 gene product is present as an indication of breast disease, Applicants will address this issue below.

Second, the Examiner states that the data presented in the specification does not prove that the overexpression of the BS106 gene product is an indication of breast disease.

Third, the Examiner states that the declaration by Dr. Paula Friedman which provided data showing the results of experiments conducted on lymph node tissues for the presence of BS106 RNA as an indication of breast disease, is not persuasive because these evidence are not provided at the time of filing the instant application.

The specification provides examples of tissues that are taken from a human in Applicants' method of detecting the presence of a BS106 product. The BS106 product is defined in the specification as stipulated by the Examiner. Applicants would like to point out to the Examiner that Applicants are permitted to be their own lexicographers. With respect to the type of tissue that is tested, the specification does not limit the tissue to be any particular kind of tissue. On the contrary, the specification states that Applicants' method of detecting breast disease is by determining whether the polynucleotides of the instant invention are present in an inappropriate body compartment. For example, page 87, line 33 - page 88, line 7 states "The BS106 polynucleotides and the proteins encoded thereby which are provided and discussed hereinabove are useful as markers of breast tissue disease, especially breast cancer. Tests based upon the appearance of this marker in a test sample such as blood, plasma, or serum can provide low cost, non-invasive, diagnostic information to aid the physician to make a diagnosis of cancer, to help selected a therapy protocol, or to monitor the success of a chosen therapy. This marker may appear in readily assessable body fluids such as blood, urine or stool as antigens derived from the diseased tissue which are detectable by immunological methods. This marker may be elevated in a disease state, altered in a disease state, or be a normal protein of the breast which appears in an inappropriate body compartment."

Applicants' new claims 85 and 86 more clearly define this aspect of the invention.

The declaration by Dr. Paula Friedman provides evidence to support Applicants' contention via the data which clearly shows the results of experiments conducted on lymph node tissues for the presence of BS106 RNA as an indication of breast disease. Applicants assert that the specification provides an adequate written support for the claimed subject matter and that they are permitted to provide evidence after the filing of the application in order to refute the Examiner's challenge.

Applicants would like to respectfully bring the following to the Examiner's attention.

The expression of a marker in a tissue or body compartment where their normal occurrence is very low or non-existent indicates that a disease has altered the marker so that it has escaped from its host tissue. Examples of markers that fall into this category are prostate specific antigen (PSA) and carcinoembryonic antigen (CEA). PSA is normally secreted at high levels into the seminal fluid and is present in very low levels in the blood of men with normal prostates. However, in patients with diseases of the prostate, including benign prostatic hyperplasia (BPH) or adenocarcinoma of the prostate, the level of PSA is markedly elevated in the blood and is a strong indication of disease of the prostate.

Similarly, CEA is a normal component of the inner lining of the colon and is present in stool and in blood at low levels in people without disease of the colon. However, in disease of the colon, including inflammatory bowel disease and adenocarcinoma of the colon, the concentration of CEA is markedly elevated in the blood plasma or serum of many patients and is an indicator of disease of that tissue (such as colorectal cancer).

Additionally, like BS106, PSA and CEA are expressed in a few tissues other than the prostate and colon. Nonetheless, these markers are still recognized as useful in the diagnosis of disease of their primary tissue of origin due to their strong tissue selectivity.

For the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claims 80-82 under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement.

Conclusion

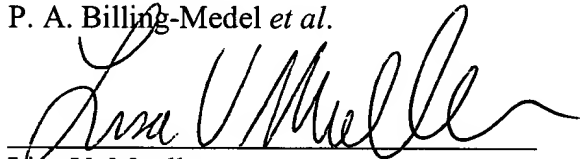
In view of the aforementioned amendments, Applicants respectfully submit that the above-referenced application is now in a condition for allowance and Applicants respectfully request that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

P. A. Billing-Medel *et al.*

A handwritten signature in black ink, appearing to read 'Lisa V. Mueller', is written over a horizontal line.

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